6 years, would be 34% lower. **CONCLUSIONS:** Treatment with nilotinib is expected to result in better health outcomes, with more patients achieving TFR. This initial TKI investment should reflect itself in long term economic benefits.

PSY13

PRE-SYMPTOMATIC GENETIC TESTING IN FAMILIAL AMYLOID POLYNEUROPATHY: THE REPRODUCTIVE OPTIONS

Inês M[1], Rodrigues F[2], Saraiva J[3], Costa J[4]

[1]*Instituto de Medicina Molecular, Lisboa, Portugal,* [2]*Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal,* [3]*Centro Hospitalar e Universitário de Coimbra, Medical Genetics Unit, Hospital Pediátrico, Coimbra, Portugal,* [4]*Institute of Molecular Medicine, Lisbon, Portugal*

OBJECTIVES: Familial Amyloid Polyneuropathy (FAP) is a rare, rapidly progressive, debilitating and life-threatening neurodegenerative disease. Pre-symptomatic genetic testing (PST) can contribute to reduce FAP prevalence, informing carriers about risk of transmission to offspring's and available reproductive options such as Pre Natal Diagnosis (PND) or Pre Implantation Genetic Diagnosis (PGD). This study aims to describe FAP carrier's reproductive options after PST and to analyse its socio-demographic determinants. **METHODS:** Data from a cohort of 145 FAP carriers that underwent PST at Medical Genetics Unit (HP/CHUC – Portugal, 2000-2012) was used to analyse reproductive options of FAP carrier's. An econometric logistic model was specified to identify determinants for natural reproduction option. **RESULTS:** The subjects were mainly women (55%) with mean age of 35 years (SD=15) at PST entry. Most participants were in a relationship 92/145 (63%) and mean number years of education was 9 years (SD=14). 75/145 (52%) of subjects were already parents, reporting a total of 144 children. 21/145 (14%) subjects decided not to have offspring following their positive test result. No child adoption was reported. 27/145 (19%) of subjects report offspring *posteriori* to PST: 19/27 (70%) subjects undergo natural reproduction and 8/27 (30%) reproduction with PND or PGD support. A total of 9 offspring non-FAP carriers (with PND/PGD) and 24 offspring from natural reproduction were observed until data collection. The logistic regression for decide on natural reproduction confirms statistical significance (p-value<0.05) for only two variables: being in relationship and having previous children. No statistical significance was observed for gender, age at PST or number of education years. **CONCLUSIONS:** There is evidence of a high proportion of carriers with offspring's when initiate PST and high proportion of natural reproduction within FAP carriers after PST. An ethical physiological case-by-case approach is essential to learn more about the determinants for preventing FAP offspring transmission.

PSY14

TRENDS IN PRESCRIPTION OPIATE USE AMONG PATIENTS WITH COMMERCIAL OR GOVERNMENT SPONSORED HEALTH INSURANCE IN THE US FROM 2010-2013

Bonafede MM[1], Palmer LA[2]

[1]*Truven Health Analytics, Cambridge, MA, USA,* [2]*Truven Health Analytics, Bethesda, MD, USA*

OBJECTIVES: To describe the prevalence of outpatient prescription opiate use among patients with Commercial, Medicare Supplemental, or Medicaid insurance in the US after 2010. **METHODS:** Patients were identified using the Truven Health Commercial and Medicare Supplemental databases from 2010-2013 and Medicaid Multi-State databases from 2010-2012. We estimated the proportion of patients with at least one outpatient opiate prescription for each calendar year among patients with continuous medical and pharmacy enrollment for the entire calendar year, stratified by insurance type and age (<18, 18-64, 65+). Average opiate days supply per calendar year was also described. **RESULTS:** On average, a total of 32.9 million (m) patients were included in each calendar year analysis with an average of 6.7m Commercially-insured children, 20.2m Commercially-insured non-elderly adults, 2.5m Medicare Supplemental adults (age 65+), 2.6m Medicaid-insured children and 0.8m Medicaid-insured adults per year. Among commercially-insured non-elderly adults, the prevalence of opiate prescriptions decreased from 25.1% to 23.4% from 2010 to 2013 (p<0.001) with a similar decrease among Medicare Supplemental patients (29.5% to 27.6%, p<0.001). Among Medicaid adults, opiate prescription prevalence was lower prevalence in 2012 (38.9%) than in 2010 (44.1%) or 2011 (45.2%). Among children (age <18), opiate prescription prevalence use was slightly higher for Medicaid than commercially-insured children (9.9% versus 7.4%, p<0.001); opiate prescription prevalence dropped by 15.3% among commercially-insured patients from 2010 to 2013 (p<0.001) and by 12.1% among Medicaid children from 2010 to 2012 (p<0.001). Average annual days supply increased over time among Medicaid adults (92.8 to 100.5 days), commercially-insured non-elderly adults (41.7 to 44.5 days) and Medicare Supplemental adults (65.9 to 68.6 days); days supply per year was steady among children (calendar year range: 7.5-9.1). **CONCLUSIONS:** There were modest reductions in the prevalence of prescription opiate use from 2010-2013. Further and more detailed monitoring is needed to parallel efforts to curtail inappropriate use.

PSY15

PREVALENCE AND TREATMENT OF CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL) IN GERMANY: AN ANALYSIS OF SICKNESS FUNDS

Tomeczkowski J[1], Leisten MK[1], Metin H[1], Khuen C[1], Fleischmann J[2], Tapprich C[1]

[1]*Janssen-Cilag GmbH, Neuss, Germany,* [2]*Janssen-Cilag Germany, Neuss, Germany*

OBJECTIVES: No national registries for chronic lymphocytic leukaemia (CLL) exist in Germany. The objective of this analysis was to examine the number of patients with CLL diagnosed (with or without other diagnoses of cancer) and to characterize the types of treatment being utilized and care settings using sickness funds claim data. **METHODS:** This analysis evaluates data from 1,771,225 beneficiaries in 2012 from different statutory sickness funds. Patients with CLL were identified by ICD-10 C91.1*, oncological co-diagnoses by ICD-10 C00-79; D37-48 and chemotherapy by Anatomical Therapeutic Chemical (ATC) Code L01*, pharmacy number (PZN) 9999092 and/or operating and procedure code (OPS) 854*. **RESULTS:** In total, 1,405 patients with a diagnosis C91.1* (CLL) were identified (prevalence 79/100,000) with 60.2% were male and 39.8% female. Overall, 32.2% of patients with CLL had a co-diagnosis with another cancer; 25.1% melanoma (C43-44), 21.3% had neoplasms with unknown behaviour (D37-48), 11.8% had malignant male GU neoplasms (90% prostate cancer) (C60-63), 10.7% had malignant neoplasms of digestive organs (C15-26) and 8,4% showed malignant neoplasms of ill-defined, secondary and unspecified sites (C76-80). The outpatient diagnosis rate for CLL was 94.9%, inpatient rate 0.6% and in-and outpatient rate 4.6%. Overall, 266 of 1,405 pts (18.9%) (175 men [65.8%], 91 women [34.2%]) received chemotherapy in 2012 (ATC Code L01* 74.1%, PZN 9999092 23.0%, OPS 854* 2.9%). Most patients received outpatient treatment (94.0%), with 5.3% of patients received both out- and inpatient treatment and 0.7% inpatient treatment. The most commonly used treatments were rituximab (26.7%), bendamustine (20.2%), chlorambucil (11.1%), cyclophosphamide (7.7%), fludarabine (6.2%) and other treatments (28.1%). **CONCLUSIONS:** The majority of patients being diagnosed with CLL did not require treatment within a time period of a year. Approximately 1/3 of patients had a second malignancy, predominantly skin cancer. Treatment was primarily composed of chemotherapy or chemoimmunotherapy.

PSY16

ACUTE MYELOID LEUKEMIA AND MYELODISPLASIC SYNDROME TREATED WITH INTENSIVE CHEMOTHERAPY IN FRANCE BASED ON NATIONAL HOSPITAL DATABASES (PMSI)

Thiebaut A[1], Lafuma A[2], Bureau I[2], Boyaval G[3], Bensoussan C[3], Godard C[3]

[1]*Department of Hematology, Grenoble University Hospital, La Tronche, France,* [2]*Cemka-Eval, Bourg la Reine, France,* [3]*MSD France, COURBEVOIE, France*

OBJECTIVES: To estimate the annual number of patients in France with Acute Myeloid Leukemia (AML) and MyeloDysplasic Syndrom (MDS) and treated with intensive chemotherapy susceptible to induce neutropenia. **METHODS:** French hospital databases named PMSI record medical information about all the hospitalizations performed annually in France. From 2006 to 2012, databases allow linking the stays over time of a given patient with an anonymous number. In this study, PMSI databases were used to identify patient, aged more than 15, with diagnosis of AML or MDS and who were alive during the year 2012. Then, patients who underwent hospital stays for chemotherapy during more than 5 days were identified and considered as neutropenic according to experts opinions. **RESULTS:** Since 2006, 51,386 patients with at least one diagnosis of AML or MDS and aged more than 15 were identified, from which only, 16,006 had at least one hospital stay in 2012 and 3,468 were hospitalized more than 5 days for chemotherapy. Among those patients, 55.2% were male, mean age was 60.4 years, 30% died during a hospital stay and 19% (664) were bone marrow grafted during the year 2012. These patients had 1.8 stays for chemotherapy per year with average chemotherapy duration of 27 days. Two third of these patients (34%) were diagnosed in 2012 and 23% in 2011. **CONCLUSIONS:** Among the 16,006 patients diagnosed AML or SMD and hospitalized in France in 2012, 3, 468 (21%) received intensive chemotherapy inducing neutropenia, putting them at high risk of invasive fungal infection.

PSY17

ALLOGENEIC STEM CELL TRANSPLANT WITH GRAFT VERSUS HOST DISEASE IN FRANCE IN 2012 BASED ON NATIONAL HOSPITAL DATABASES (PMSI)

Thiebaut A[1], Lafuma A[2], Bureau I[2], Boyaval G[3], Bensoussan C[3], Godard C[3]

[1]*Department of Hematology, Grenoble University Hospital, La Tronche, France,* [2]*Cemka-Eval, Bourg la Reine, France,* [3]*MSD France, COURBEVOIE, France*

OBJECTIVES: To estimate the number of patients receiving Allogeneic Stem Cell Transplant (ASCT) and presenting with graft versus host disease (GVHD) in 2012 in France. **METHODS:** French hospital databases named PMSI record medical information about all the hospitalizations performed annually in France. From 2006 to 2012, databases allow linking the stays of a given patient over time with an anonymous number. In this study, PMSI databases were used to identify patient, aged more than 15, with allogeneic stem cell transplant through adequate Diagnosis Related Group and who were alive, hospitalized during the year 2012. Patients with diagnosis of GVHD or typical diagnoses of GVHD symptoms (sclerodermia, diarrhea, mucitis and keratitis) were identified. **RESULTS:** Since 2006 to 2012, 9,855 patients received allogeneic stem cell transplant in France of which 3,469 died during a hospitalization over the period, with an annual death rate stable around 20%. In 2012, 3,842 ASCT patients aged more than 15 were hospitalized at least once, and the proportion with GVHD was estimated to 40% (1,574). Acute GVHD diagnosis or typical GVHD symptoms occurring less than 100 days after grafting appeared in 274 patients and chronic GVHD was diagnosed in 1300 patients. Mean age was 47.8, 61.4% were male and 22% of these patients died during a stay in 2012. Among the ASCT patients hospitalized in 2012, only 5% were grafted in 2006 and this figure regularly increased with the year of the procedure to reach 35% grafted in 2012, corresponding to a mean annual mortality rate of around 20%. **CONCLUSIONS:** Among the 3,842 ASCT patients hospitalized in France in 2012, 1,574 (40%) presented GVHD, putting them at higher risk of immunosuppression and invasive fungal infection, but also at higher risk of death.

PSY18

THE PRESENCE OF ANXIETY AMONG ELEMENTARY SCHOOLS OBESE CHILDREN

Germán Z[1], Botár A[2], Szíládiné Fusz K[1], Pakai A[3], Boncz I[4], Fullér N[1], Oláh A[1]

[1]*University of Pécs, Pécs, Hungary,* [2]*Balassa János Hospital, Szekszárd, Hungary,* [3]*University of Pécs, Zalaegerszeg, Hungary,* [4]*Faculty of Health Sciences, University of Pécs, Pécs, Hungary*

OBJECTIVES: From among the consequences of the obesity very considerable the emotional and distressful disturbances with which it grew fat children day, than day they fight. Assessing a what kind of measure the sport influences it on was our aim the nutritional and the mood life, furthermore, that the obesity influences the learning and the mood life. **METHODS:** We made a questionnaire survey in the primary schools of Szekszárd, 13-14 year ones among students. Inclusion it was a criterion that only 7-8. are class children may have taken a part in the examination, furthermore without parents consent, and sufferers may not have taken a part in the examination only in a serious illness. All element 149 heads. At the compilation of the questionnaire used Helena (Healthy Lifestile in Europe by Nutritrion in Adolescence) name from a project for us essential questions, and we complemented it their edited our questionnaire implied altogether 150 questions with questions,

so. **RESULTS:** Our 1. hypothesis, that the children with normal weight move much, than their obese companions, not proven true (p=0,778). It was the next supposition that less are truth with a subject for the students with normal weight they have difficulties, than for the obese students. According to the examination, the normal one and the obese child with a subject truth in the look of difficulty, we found a significant difference (p=0,015). The third hypothesis, that, in the obese group taller the anxious children's proportion, than the did not grow fat in a group, not proven true. The overweight children (n=46, medium=109, 76) anxiety with a significantly bigger degree was not showed based on the scale the normal one tápláltsági state at students (n=95, medium=104, 56 dot, p=0,515). **CONCLUSIONS:** The enrolled students showed no significant difference between the observed parameters of the overweight and sporting habits.

SYSTEMIC DISORDERS/CONDITIONS – Cost Studies

PSY20
CLINICAL AND COST-EFFECTIVENESS AND BUDGET IMPACT OF ROUTINE USE OF BISPECTRAL INDEX MONITORS IN THEATRES

Vincent O[1], Sabatelli L[2], Craig J[1], Taylor M[1]
[1]*York Health Economics Consortium, York, UK,* [2]*GLOB MOD, Barcelona, Spain*

OBJECTIVES: Bispectral Index (BIS) monitoring systems monitor spontaneous electroencephalography, track sedative drug effects and help guide anaesthetic administration. Evidence shows such monitoring enables savings on anaesthesia and reduces adverse events compared with monitoring clinical signs only. However, the cost-effectiveness of monitors is uncertain. **METHODS:** A cost-effectiveness model and budget impact analysis were developed to compare the outcomes of monitoring the depth of anaesthesia with BIS monitors compared with standard clinical monitoring. Over a five-year period, the model estimated the incremental cost per quality-adjusted life year (QALY) and incremental number of adverse events avoided in theatres with anaesthetists using BIS monitors compared with standard care. Data values were obtained from peer-reviewed literature. Subgroup analysis was conducted for an elderly patient group. Sensitivity analyses explored uncertainty in the model. A budget impact model examined the financial impact of adopting BIS monitors across the UK. **RESULTS:** The modelled results showed that using BIS monitors dominated clinical observation of signs and use of electrocardiograph and other devices, being cost saving by £82 per operation in the adult population, whilst improving QALYs by 0.016 per patient. The budget impact analysis showed a cumulative saving of over £136 million if theatres in the UK adopted a phased increase in monitor use such that 1.35 million surgical procedures were conducted using these monitors in five years time. **CONCLUSIONS:** Adopting BIS monitors is cost-effective and results in substantial cost savings compared with observing clinical signs plus conventional devices only.

PSY21
ESTIMATING THE COSTS OF DRUG SUPPLY FOR RARE DISEASES PATIENTS IN RUSSIA

Sura M[1], Gerasimova K[1], Omelyanovsky VV[1], Avxentyeva M[1], Tatarinov A[2], Fedyaev D[2]
[1]*The Russian Presidential Academy of National Economy and Public Administration, Moscow, Russia,* [2]*Financial Scientific Research Institute of the Ministry of Finance of Russia, Moscow, Russia*

OBJECTIVES: To estimate the costs of drug supply for registered rare diseases (RD) patients in Russia in 2013. **METHODS:** The study included two steps: 1) the analysis of the current situation with financing of drugs for RD patients in Russia in 2013 and 2) estimating the unmet needs - necessary weighted average costs (nWAC) for a pathogenetic pharmacotherapy of registered patients with RD in the same year. Number of registered patients with 24 RD listed in the Government Regulation of Russian Federation №403 from April 26, 2012 was estimated for the studied year. Number of registered patients and actual financing has been received from the database of regional public health services. The nWAC for expensive pathogenetic pharmacotherapy of patients with 24 RD were calculated on the basis of standards of therapy and experts' survey results. The current situation with financing of RD drugs in Russia in 2013 was compared with unmet needs (nWAC). **RESULTS:** 4.4 billion rubles ($125.7 million) were spent from regional budgets in Russia for 11,173 patients (0.008% from all population of Russia) with 24 RD in 2013. The largest patient group with 3,460 patients was a classic phenylketonuria group. The prognostic annual nWAC for pharmacotherapy of the most expensive patient with type VI mucopolysaccharidosis were 40.9 million rubles ($1.2 million) per child and 71.5 million rubles ($2.0 million) per adult. The nWAC for pharmacotherapy of registered patients with 24 RD in 2013 were 15.7 billion rubles ($448.6 million). The annual nWAC for pharmacotherapy of the most expensive disease (idiopathic thrombocytopenic purpura (Evans syndrome) was estimated as 2.9 billion rubles ($82.8 million) per group of 2,700 patients. **CONCLUSIONS:** The state financing of pharmacotherapy for patients with 24 RD in Russia should be increased approximately in 3.5 times to fulfill the unmet needs.

PSY22
BUDGET IMPACT ANALYSIS OF DRUGS FOR ULTRA-RARE NON-ONCOLOGICAL DISEASES IN EUROPE

Schlander M[1], Gandjour A[2]
[1]*University of Heidelberg, Wiesbaden, Germany,* [2]*Frankfurt School of Finance & Management, Frankfurt, Germany*

OBJECTIVES: Ultra-rare disorders (URDs) have been defined by a prevalence of less than 1 per 50,000 persons. On a per patient basis, the annual acquisition costs of drugs for URDs can be very high, and there have been concerns that expenditures for these products might escalate in the future. The goal of this study was therefore to provide a budget impact analysis (BIA) of drugs for ultra-rare non-oncological diseases in Europe. **METHODS:** The BIA had a time horizon of 10 years (from 2012 to 2021) and adopted the perspective of all European payers in combination. The estimate was based on prevalence data for URDs for which patented drugs are currently available and for which drugs are in clinical development and hence may be expected to be launched in the foreseeable future. A power function was used to estimate the relation between (decreasing) prevalence and (increasing) cost per patient. For drugs in development, we applied phase duration data and attrition rates from the Tufts Center for the Study of Drug Development database. **RESULTS:** A total of 18 drugs under patent protection for non-oncological URDs were identified. Furthermore, 29 drugs for non-oncological URDs under development that have the potential of reaching the market by 2021 were found. Total budget impact over 10 years was estimated to be €14,112 and €4,965 million for approved and pipeline URD drugs, respectively (total: €19,077 million). Relative to total pharmaceutical expenditures in Europe, spending on drugs for URDs is estimated to rise from 0.7% at present to 1.6% in 2021. Univariate sensitivity analyses and extreme scenario analyses suggesting robustness of this projection will be presented. **CONCLUSIONS:** Our analysis does not support concerns regarding an uncontrolled growth in expenditures for drugs for URDs. Nevertheless, continuous monitoring of the budget impact as an input to rational policy making is recommended.

PSY24
BUDGET IMPACT OF ORPHAN DRUGS IN THE NETHERLANDS IN THE PERIOD 2006-2012

Kanters TA, Steenhoek A, Hakkaart L
Erasmus University Rotterdam, Rotterdam, The Netherlands

OBJECTIVES: The relatively low budget impact of orphan drugs is often used as an argument in reimbursement decisions. However, overall, the budget impact of orphan drugs can still be substantial. In this study, we assess the uptake and budget impact of orphan drugs in the Netherlands. **METHODS:** We examined the number of orphan drugs, the number of patients and budget impact of orphan drugs in the Netherlands in the period 2006 to 2012, both for inpatient and outpatient orphan drugs. Budget impact was provided in absolute numbers and relative to total pharmaceutical spending. **RESULTS:** The number of orphan drugs and patients treated increased substantially over the period studied. Overall, budget impact increased substantially over a period of six years, both in absolute terms (426% increase) as well as relative to total pharmaceutical spending (378% increase). Growth rates decreased over time. In 2012, 17% of available drugs had an individual budget impact of more than €10 million per year. **CONCLUSIONS:** Individual budget impact of orphan drugs is often limited, although exceptions exist. However, in total, the budget impact of orphan drugs is considerable and has grown substantially over the years. This could potentially influence reimbursement decisions for orphan drugs in the future.

PSY25
BUDGET IMPACT ANALYSIS OF INTRODUCING BIOSIMILAR INFLIXIMAB FOR THE TREATMENT OF AUTO IMMUNE DISORDERS IN FIVE EUROPEAN COUNTRIES

Jha A[1], Upton A[2], Dunlop W[1]
[1]*Mundipharma International Limited, Cambridge, UK,* [2]*Abacus International, Bicester, UK*

OBJECTIVES: Biosimilar infliximab has been approved by EMA for the management of inflammatory autoimmune disorders including rheumatoid arthritis (RA), ankylosing spondylitis (AS), Crohn's disease, ulcerative colitis (UC), psoriatic arthritis (PsA), and psoriasis based on quality, safety and efficacy profiles comparable to infliximab. The aim of this study was to evaluate the five-year budget impact of introducing biosimilar infliximab in the management of RA, AS, Crohn's disease, UC, PsA, and psoriasis from the health care system perspective. **METHODS:** An Excel-based budget impact model was developed. The numbers of patients eligible for infliximab were calculated based on disease prevalence rates in Germany, Italy, Belgium, the Netherlands and the United Kingdom. The price of biosimilar infliximab is not yet known; therefore three discount scenarios versus infliximab (10%, 20%, and 30%) were applied. Market share was assumed to be 25% in the first year in all scenarios. Annual market share growth was varied in each of the scenarios at 20%, 30% and 40%, respectively. **RESULTS:** The combined net budget savings for Germany, Italy, Belgium, the Netherlands and the United Kingdom in the first year were €17.8, €35.5 and €53.3 million for the 10%, 20% and 30% price discount scenarios, respectively. Over a 5 year period the net budget savings were €132.8, €322.8 and €532.8 million for the 10%, 20% and 30% price discount scenarios, respectively. **CONCLUSIONS:** The introduction of biosimilar infliximab as a treatment option for patients with RA, AS, Crohn's disease, UC, PsA, and psoriasis could achieve substantial cost savings for health care systems. In the price discount scenarios tested, the total combined savings across Germany, Italy, Belgium, the Netherlands and the United Kingdom over a 5 year period ranged from €132.8 million to €532.8 million. The net budget impact was highly sensitive to market uptake rates and the price discount applied.

PSY26
BUDGET IMPACT ANALYSIS OF BELIMUMAB IN THE TREATMENT OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS IN RUSSIAN FEDERATION

Kulikov A, Komarov I, Pochuprina A
I.M. Sechenov First Moscow State Medical University, Moscow, Russia

OBJECTIVES: To estimate budget impact analysis (BIA) of belimumab plus standard of care (SoC) comparing the SoC alone in the treatment of patients suffering from systemic lupus erythematosus (SLE). **METHODS:** BIA was conducted of the belimumab treatment plus SoC vs SoC alone. Costs of treatments in both groups contained following direct medical costs: costs of drugs and administration, costs of diagnostic laboratory and instrumental procedure, costs of inpatient and outpatient visits, costs of SLE complications and also adverse event costs. A five-year time horizon was used. All costs in both groups were estimated to their present value using a 5 % discount rate. **RESULTS:** Costs of the course of belimumab therapy were 2,118,449 RUB/ 45,581 EUR for 5 years but the difference in the required budget funds between belimumab treatment groups and SoC alone treatment group amounted to 1,876,965 RUB/ 40,385 EUR for 5 years with a 5 % discount rate. The decrease of the difference in the required budget funds between these two groups was due to a lower